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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,543	02/12/2004	Harold M. Bates	C015043/0174944	9840
7590 Stephen P. Gilbert, Esq. BRYAN CAVE LLP 1290 Avenue of the Americas New York, NY 10104			EXAMINER VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/777,543

Applicant(s)

BATES, HAROLD M.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 13, 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-13, 15-30, 32-34 and 36-88 is/are pending in the application.
- 4a) Of the above claim(s) 43-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 15-30, 32-34 and 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11-13, 15-30, 32-34 and 36-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :08/29/06; 09/05/06; 05/26/06; 11/10/05; 06/17/05; 06/23/04; 02/12/04; 06/18/04.

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DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicant's reply filed November 13, 2006. Applicant elects Invention I, claims 1-9,11-13,15-30,32-34 and 36-42, with traverse. Applicant traverses on the grounds that "applicant does not understand why the Examiner said Invention I (the Group I claims) 'requires a contradiction' and why the Group I claims are 'indefinite'" (see Applicants' reply, p. 2, fourth paragraph). Applicant then illustrates said contradiction (see Applicants' reply, p. 3, top of page).

The restriction requirement is considered proper and is made FINAL.

Claims 43-88 are drawn to a non-elected invention and are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim. Currently, claims 1-9,11-13,15-30,32-34 and 36-42 are under examination.

Information Disclosure Statement

The information disclosure statements filed February 12, 2004, June 18, 2004, June 23, 2004, November 10, 2005, May 26, 2006, September 5, 2006, and August 29, 2006, fail to comply with the provisions of 37 CFR § 1.98(b)(5). According to Section 1.98(b)(5), each publication listed in an information disclosure statement must be identified by publisher, authors, title, relevant pages, date, place of publication, (e.g., publisher, authors, title, relevant pages, date, place of publication). Examiner has not considered most of the 130+ publications in any of the disclosures.¹

¹ Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the

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Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Insofar as claims 1 and 22 do not require "patients",² Examiner interprets the verbiage in claims 1 and 22 as non-statutory "abstract ideas" in accordance with M.P.E.P. § 2106.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

Insofar as claims 1 and 22 do require "patients",³ claims 1 and 22 require, *inter alia*, patients having an "asymptomatic disease" (*i.e.*, asymptomatic coronary artery disease). Claims 1 and 22 create a semantic construct wherein a person simultaneously has a disease, yet is asymptomatic for that disease.

Applicant's specification asserts, *inter alia*, that methods incorporating "asymptomatic diseases" are useful for "discrimination between those who have coronary artery disease and those who do not" (see p. 15, lines 21-22).

requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

² See Applicant's reply, p. 6, first paragraph, "The methods of claims 1 and 22 comprise steps, *not patients*[...]"; second paragraph, "the methods of claims 43 and 66 comprise steps, *not patients*[...]" (emphasis in original) (paraphrasing mine).

³ *Id.*

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According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicant's assertion of utility is premised on data obtained from a clinical study involving persons belonging to two semantic classes of individuals:

1. healthy (see *e.g.*, Table III, "Controls"; see *also*, p. 44, lines 3-4, "For purposes of evidencing the advantages of this invention, the assumption can be made that those in the control group are true negatives");
2. not healthy, *i.e.*, diseased (see *e.g.*, Table III, "Stable angina", "Unstable angina", "AMI")

Applicant's specification does not disclose any semantic class of individuals who are simultaneously healthy and not healthy (*i.e.*, individuals with asymptomatic diseases), much less any clinical data involving any asymptomatic disease, much less a useful method based on such (non-existent) clinical data.

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Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first and second paragraphs of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credibly asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Throughout the claims, the phrase "related to" is indefinite. The identity of one or more standards for satisfaction of "related to" is not clear.

In preambles of claims 1 and 22 do not correspond to their respective method outcomes. For example, step (c) of claim 1 requires a step of performing "assessing" based on one or more comparisons. Whether/how mere "comparison", absent baselines or reference values for comparison, amounts to an "assessment of the likelihood that a human patient who is asymptomatic for coronary artery disease has the disease" is not clear.

In claim 22, step (d), the infinitives "to permit" and "to assess" are indefinite. Whether the act or process of "permitting" or "assessing" are completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing "permitting" or "assessing" is/are not clear.

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Conclusion

No claims are allowed at this time.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kaplan & Sadock, SYNOPSIS OF PSYCHIATRY, Lippincott Williams & Wilkins, 8d. (1998), are cited for their description of an "asymptomatic disease" (see p. 637, left column, "hypochondriasis").

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


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